IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

GENZYME CORPORATION,	)	
Plaintiff,	)	
v.	)	Civil Action No.: JFM-09-cv-1750
SANDOZ, INC.	)	
Defendant.	)	

GENZYME'S REPLY BRIEF IN SUPPORT OF ITS MOTION TO DISMISS COUNTS III AND IV OF SANDOZ'S COUNTERCLAIM ON THE '780 PATENT

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INTRODUCTION

Sandoz does not have an unfettered right pursuant to the Hatch-Waxman Act to challenge the '780 patent; the Act does not circumvent the "irreducible constitutional minimum of standing." Under the Constitution, Sandoz must prove the existence of an actual Article III controversy in order for this Court to have subject matter jurisdiction and Sandoz to have standing. This, in turn, requires that Sandoz prove that it is suffering a concrete injury in fact. Sandoz cannot do so.

Sandoz cannot, contrary to its allegations, suffer either the injury in fact that conferred standing in *Teva* or that in *Caraco*. There is no threat to Sandoz of multiple infringement suits—the injury in fact in *Teva*—because, unlike in *Teva*, Genzyme granted Sandoz a covenant not to sue on the '780 patent. And, Sandoz will not be unjustly prevented from hastening its market entry—the injury in fact in *Caraco*. That is so because Sandoz filed Paragraph III certifications on the 2013 patents, meaning it cannot—under any circumstance—enter the market until those patents expire in 2013.

With dismissal of its declaratory judgment action on the '780 patent, the only non-speculative delay—and potential "harm"—Sandoz faces is a delay in final FDA approval due to Endo's first-filer exclusivity. However, it is unquestionable that such delay is an intended result of the Hatch-Waxman Act and—according to the Federal Circuit in *Janssen*—does not constitute an injury in fact. Sandoz cannot escape this binding precedent.

Sandoz's *only* identified alleged harm—losing the opportunity to become the *first* to market a generic copy of Renagel®—cannot confer standing in this case because it is too speculative. There is no non-speculative course of events that would

allow Sandoz to enter the market *before* the first filer Endo. Sandoz placed itself on exactly the same footing as Endo by filing Paragraph III certifications on the 2013 patents; neither Sandoz nor Endo can receive final FDA approval before those patents expire. Moreover, if Sandoz's declaratory judgment action on the '780 patent is not dismissed, it could destroy Endo's exclusivity and remove the regulatory barrier it presents. But, this would only allow Sandoz to enter the market at the *same time* as—and *not before*—Endo and all other existing Renagel® ANDA filers.

The Hatch-Waxman Act strikes a careful balance between the dual goals of encouraging development of innovative drugs and enabling the marketing of generic drugs. Congress awarded the *first* ANDA filer a 180-day period of generic market exclusivity to achieve this end. Here, Endo was the first generic company to file an ANDA— Sandoz was *not*—and Endo is entitled to 180-days exclusivity.

Sandoz's stated goal in bringing its declaratory judgment action is to trigger the forfeiture of Endo's first-filer exclusivity. In *Janssen*, the Federal Circuit emphasized the importance of preserving exclusivity as an incentive to generic drug companies. Given the absence of any injury in fact, Sandoz's declaratory judgment action can only serve to frustrate the aims of the Hatch-Waxman Act by depriving Endo of the statutory reward for its early filing.

For the above reasons, Sandoz has clearly failed to meet its burden of proving a concrete injury in fact with respect to the '780 patent. Moreover, Sandoz cannot ask that this Court nonetheless exercise its discretion to hear Sandoz's declaratory judgment action because when—as here—there is no injury in fact and no Article III controversy, the Court has no such discretion. Genzyme's motion should be granted.

ARGUMENT

I. There Is No Subject Matter Jurisdiction Over The '780 Patent

Sandoz asserts that "[d]eclaratory judgment jurisdiction exists in this case because Sandoz has the ability to challenge the '780 patent under the Hatch-Waxman Act and the potential to be the first to enter the market for generic Renagel®." (Sandoz Opp'n 14.) Sandoz does not, however, have the ability under the Hatch-Waxman Act to challenge the '780 patent in the absence of a concrete injury in fact. And, the cases Sandoz relies upon—*Teva* and *Caraco*—are inapposite; Sandoz cannot suffer the same injuries in fact that conferred standing in those cases. (Sandoz Opp'n 11-16.) Moreover, Sandoz is wrong in asserting that it could be the first to market a generic copy of Renagel®. Sandoz's alleged harm—losing the opportunity to become this first market entrant—amounts to nothing more than pure speculation.

A. Sandoz Cannot Establish Subject Matter Jurisdiction In The Absence Of An Injury In Fact

Contrary to Sandoz's assertions of a "clear right," Sandoz does not have an unfettered ability to challenge the '780 patent under the Hatch-Waxman Act. (Sandoz Opp'n 23; *see also* Sandoz Opp'n 5, 6, 10, 14.) Consistent with the U.S. Constitution, the Hatch-Waxman Act extended federal court jurisdiction to hear declaratory judgment actions in the ANDA context *only* to the extent that they present an actual Article III controversy. 35 U.S.C. § 271(e)(5); 28 U.S.C. § 2201. An Article III controversy requires that, under all the circumstances, the dispute be definite and concrete. *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 771 (2007). To meet this standard, the declaratory judgment plaintiff—Sandoz—must prove, *inter alia*, that it has standing

to bring the action.[1] This, in turn, requires that Sandoz suffer an injury in fact; that is, an injury that is "'concrete' and actual or imminent, not 'conjectural' or 'hypothetical.'" *Caraco Pharm. Labs., Ltd. v. Forest Labs., Ltd.*, 527 F.3d 1278, 1291 (Fed. Cir. 2008). The Hatch-Waxman Act does not allow Sandoz to circumvent this "irreducible constitutional minimum of standing." *Id.*

1. Sandoz Cannot Suffer The Same Injury In Fact That Created Standing And The Article III Controversy In *Teva*

Citing *Teva*, Sandoz asserts that it has standing to bring this declaratory judgment action merely because Genzyme listed the '780 patent in the Orange Book and is not asserting the patent against Sandoz. (Sandoz Opp'n 12.) However, Sandoz ignores that Genzyme has granted it a covenant not to sue on the '780 patent. The existence of a covenant not to sue is a "significant distinction" from *Teva*. *Merck & Co. v. Apotex, Inc.*, 488 F. Supp. 2d 418, 423 (D. Del. 2007), *affirmed-in-part, vacated-in-part as moot*, 287 Fed. App'x 884, 888-89 (Fed. Cir. 2008). The covenant not to sue on the '780 patent removes from this case the injury in fact—the threat of multiple infringement suits based on a single ANDA—that the second-filer suffered in *Teva*.

In *Teva*, Novartis had listed five patents in the Orange Book in connection with its innovative drug product. *Teva Pharm. U.S.A., Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1334 (Fed. Cir. 2007). One of the listed patents was due to expire in

[1] The Supreme Court's three-part framework provides that an action is justiciable under Article III only where (1) the declaratory judgment plaintiff has standing, (2) the issues presented are ripe for judicial review and (3) the case is not rendered moot at any stage of the litigation. *Caraco*, 527 F.3d at 1291. The Supreme Court has also explained that standing has three requirements: (1) an injury in fact; (2) causation—a fairly traceable connection between the plaintiff's injury and the complained-of conduct of the defendant; and (3) redressability—a likelihood that the requested relief will redress the alleged injury. *Id.*

2010 and the remaining four in 2014 or 2015. *Id*. Teva filed Paragraph IV certifications for all five of the listed patents; Novartis sued for infringement of only the earliest expiring patent. *Id*. at 1334-35. Novartis refused to give Teva a covenant not to sue on the remaining four patents and Teva brought a declaratory judgment action in respect of them. *Id*. at 1335. The Federal Circuit held, under the *MedImmune* "all the circumstances" standard, that there was an injury in fact and therefore a justiciable Article III controversy. *Id*. at 1340.

Teva's injury in fact was the threat of protracted litigation on the remaining patents. In the absence of a covenant not to sue, Novartis could—at any time—sue Teva for infringement of the unasserted patents under 35 U.S.C. § 271(e)(2)(A) or § 271(a). *Id*. at 1341-42. By selectively suing Teva on only the earliest expiring patent, Novartis had left the remaining four patents, which would expire up to five years after the asserted patent, "overhanging Teva for future litigation." *Id*. at 1340 n.5. However, a covenant not to sue eliminates the threat of multiple infringement suits on a single ANDA. *Id*. at 1343.

By granting Sandoz a covenant not to sue on the '780 patent, Genzyme has eliminated any threat that it will sue Sandoz for infringement of that patent in the future. If and when Sandoz receives final FDA approval for its ANDA, Sandoz will be able to launch its generic copy of Renagel® free from any restraint imposed by the '780 patent. Accordingly, the covenant not to sue ensures that Sandoz cannot suffer the same injury in fact that created standing and the Article III controversy in *Teva*.

2. Sandoz Cannot Suffer The Same Injury In Fact That Created Standing And The Article III Controversy In *Caraco*

Sandoz next argues that the holding in *Caraco* stands for the proposition that "when patentees sue on less than all of the listed patents and use a [covenant not to sue] instead of the statutorily recognized settlement order or consent decree in resolving disputes, jurisdiction still exists for defendants to join other listed patents." (Sandoz Opp'n 14.) The holding in *Caraco* is not so expansive.

In *Caraco*, the first-filer had been found to infringe the first patent, while the second-filer had the potential to prevail on noninfringement of that patent. *Caraco*, 527 F.3d at 1297. Without the ability to challenge the second patent, the second-filer could have been blocked from entering the market for the remainder of the term of the first patent—even if it did not infringe that patent—by the 180-day exclusivity associated with the second patent. That is because, having lost its challenge to the first patent, the first-filer could not launch until that patent expired. The first-filer's exclusivity—based on its challenge to the second patent—precluded any second-filer from obtaining final FDA approval and entering the market before the first-filer. In this way, the second-filer was prevented from launching even if it did not infringe the first patent. Thus, the injury in fact faced by the second-filer was the potential to be excluded from the market by a patent it did not infringe. *Id.*

The covenant not to sue that the patentee had granted to the second-filer did not eliminate this injury. *Id.* But, through a successful challenge to infringement of the first and second patents, the second-filer had the potential to hasten its entry to the market and launch prior to the first-filer, who could *not* market its product prior to

expiration of the first patent because it was unsuccessful in its challenge of that patent. *Id*. That is not—as explained below—the case here.

The injury in fact in *Caraco* was not a delay due solely to the proper exercise of the first-filer's 180-day exclusivity. That delay was addressed in *Jansen* and the court held that delay in a second-filer's—such as Sandoz's—final FDA approval and market entry due to the first-filer exercising its statutory entitlement to exclusivity was an intended result of the Hatch-Waxman Act and did not constitute an injury in fact. *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1361 (Fed. Cir. 2008).

Here, Endo was the first to file a Paragraph IV certification with respect to any of the Orange Book-listed patents and is therefore entitled to 180 days of generic market exclusivity under the Hatch-Waxman Act. 21 U.S.C. § 355(j)(5)(B)(iv); *see also Janssen*, 540 F.3d at 1358. Sandoz and Endo both filed Paragraph III certifications in respect of the 2013 patents;[2] thus, neither can receive final FDA approval before the expiration of those patents in August 2013. 21 U.S.C. § 355(j)(2)(A)(vii)(III); *see also Janssen*, 540 F.3d at 1358. Unlike in *Caraco*, Sandoz cannot hasten its market entry here because that entry cannot occur before the 2013 patents expire.

Moreover, Sandoz and Endo are actively challenging the validity and infringement of the '775 patent, which expires in September 2014. Such challenges will certainly stand or fall together.[3] Accordingly, final FDA approval of Sandoz's ANDA

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[2] Genzyme listed six patents relating to Renagel® in the Orange Book. Four of these patents, U.S. Patent Nos. 5,496,545; 6,509,013; 7,014,846; and 7,459,151 expire in August 2013. They are referred to herein as the "2013 patents."

[3] The patent in issue is the same: the '775 patent; and the products are the same: generic copies of Genzyme's Renagel® product. As explained in more detail below at pp.11-12, it is inconceivable—and Sandoz has not even tried to explain how it could

can occur on one of two dates both of which *only* implicate a delay to Sandoz's FDA approval due to Endo's 180-day exclusivity:

- If the '775 patent is found invalid or not infringed, the FDA will approve Endo's ANDA on expiration of the 2013 patents, Endo can then launch and Sandoz will receive approval 180 days later.[4]
- If the '775 patent is found valid and infringed, the FDA will approve Endo's ANDA on expiration of the '775 patent, Endo can then launch and Sandoz will receive approval 180 days after that.

Sandoz is thus wrong that this case is analogous to *Caraco*. (Sandoz Opp'n 14.) That is because even if Sandoz were permitted to continue with its declaratory judgment action on the '780 patent, and even if Sandoz were successful in that action, Sandoz's Paragraph III certifications on the 2013 patents would still block Sandoz from entering the market. Moreover, the '780 patent is not blocking Sandoz from receiving timely final FDA approval. With dismissal of its declaratory judgment action on the '780 patent, the only non-speculative delay Sandoz faces in final FDA approval—and market entry—is due to Endo's 180-day exclusivity. Such delay was intended by the Hatch-Waxman Act and does not represent an injury in fact. *Janssen*, 540 F.3d at 1361-62.

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happen—that this Court will reach divergent results under these circumstances. This too is a significant distinction from *Caraco*.

[4] In its Statement of Facts, Sandoz speculates that Endo "may" delay launching after it receives final FDA approval and thereby delay generic competition until expiration of the '780 patent in 2020. (Sandoz Opp'n 10.) However, the Federal Circuit considered and rejected this alleged harm in *Janssen* because it was too speculative. *Janssen*, 540 F.3d at 1362-63. Similarly, here, there is no basis to conclude that Endo will delay launching after final FDA approval of its ANDA (as Sandoz's description of the possibility—its use of the word "may"—inadvertently reveals).

3. Following *Janssen*, Sandoz's Paragraph III Certifications On The 2013 Patents Remove Any Injury In Fact

Sandoz seeks to avoid *Janssen's* binding precedent by suggesting that it applies only where the second-filer does something to destroy jurisdiction. (Sandoz Opp'n 16-17.) However, *Janssen* is not so limited. In that case, the Federal Circuit held that a second-filer's inability to hasten market entry because of the first-filer's 180-day exclusivity period does not create a cognizable Article III controversy. *Janssen*, 540 F.3d at 1361-62. Where the *only* alleged "harm" to the second-filer is the delay in market entry that is an intended result of the Hatch-Waxman Act, courts do not have subject matter jurisdiction. *Id*. In any event, by filing Paragraph III certifications in respect of the 2013 patents, Sandoz placed itself in the same position as the second-filer in *Janssen* and thereby removed subject matter jurisdiction from this case.

The key difference between *Caraco* and *Janssen* was that, having stipulated to the validity and infringement of the earlier-expiring first patent, the second-filer in *Janssen* could not claim that it was being prevented from hastening its market entry by a potentially invalid or not infringed patent. *Id*. at 1361. As Sandoz recognizes, the stipulation rendered second-filer Apotex's declaratory judgment action "impotent" because even if Apotex prevailed on the later-expiring second patent, the first patent—which Apotex conceded was valid and infringed—was still blocking FDA approval and market entry. (Sandoz Opp'n 17.)

Similarly, in this case, Sandoz cannot complain that it is being unjustly excluded from the market by the absence of a decision on the "second patent"—the '780 patent. By filing Paragraph III certifications, Sandoz chose to respect the expiration dates of the 2013 patents—the "first patent"—and has in effect stipulated to their validity and

infringement. Any declaratory judgment on the '780 patent will be "impotent" because the Paragraph III certifications on the 2013 patents will block FDA approval and market entry. A successful challenge to the '780 patent by Sandoz will *not* accelerate generic market entry—as in *Caraco*—but could only destroy Endo's 180-day exclusivity—as in *Janssen*.

The '775 patent does not change the analysis because Sandoz's challenge to this patent stands or falls with those of the other Renagel® ANDA filers.[5] (Sandoz Opp'n 18.) Sandoz and the other Renagel® ANDA filers—Endo, Impax and Lupin—are actively challenging the '775 patent. If the '775 patent is found to be either invalid or not infringed, then any regulatory barrier presented by this patent will be removed. As discussed in Genzyme's Opening Brief and further below, it is inconceivable that this Court will find the '775 patent valid and infringed with respect to one defendant and invalid or not infringed with respect to the others. (Genzyme Opening Br. 12-14.) Under these circumstances, there is also no chance that Sandoz will be excluded from the market by an invalid or not infringed '775 patent; the '775 patent is not the "first patent" in the *Caraco* analysis.

Like *Janssen*, this case is materially different from *Caraco* and there is no injury in fact.

[5] In addition to Sandoz, there are two further second-filers in this case—Impax and Lupin. Like Sandoz, they filed Paragraph III certifications in respect of the 2013 patents and, accordingly, cannot received final FDA approval before these patents expire in August 2013. 21 U.S.C. § 355(j)(2)(A)(vii)(III); *see also Janssen*, 540 F.3d at 1358.

B. Sandoz Has Failed To Identify Any Non-Speculative Harm Which Constitutes An Injury In Fact

As noted above, Sandoz asserts that it has the potential to be the first to enter the market for generic Renagel® and will suffer an injury in fact if it loses this opportunity. (Sandoz Opp'n 17-19.) It is, however, wrong to suggest that Sandoz can receive final FDA approval and launch its generic Renagel® copy *before* Endo. The best outcome for which Sandoz can hope—if Sandoz is permitted to destroy Endo's first-filer exclusivity—is to obtain final FDA approval at the *same time* as Endo and all other existing Renagel® ANDA filers.

1. Sandoz Cannot Enter The Market *Before* Endo

Sandoz alleges that it could enter the market *before* Endo if Sandoz wins its case on the '775 patent and Endo either (1) loses, or (2) settles. (Sandoz Opp'n 17.) However, neither of Sandoz's scenarios set forth a non-speculative course of events that would allow Sandoz to enter the market *before* Endo. Therefore, Sandoz cannot meet its burden of proving the existence of an injury that is concrete, not merely conjecture. *See Caraco*, 527 F.3d at 1291.

As to the first scenario, in order for Sandoz to win on the '775 patent and for Endo to lose, this Court would need to reach different conclusions on the validity or infringement of the '775 patent in the two respective litigations. It is unreasonable to argue that this outcome could occur. *First*, patent validity is not case dependent; if this Court finds the '775 patent invalid in one case, it is invalid for all cases. *Second*, there is no possibility of divergent infringement findings. As explained under scenario 4 in Genzyme's Opening Brief, Endo's product is substantially identical to Sandoz's—they are generic copies of Genzyme's Renagel® product. (Genzyme Opening Br. 12-14.) If

Endo infringes, so too does Sandoz. Sandoz has failed to provide *any* basis for finding noninfringement of the '775 patent and absolutely *no* basis from which this Court can conclude Sandoz's product may not infringe the '775 patent, but Endo's will.

As to the second scenario, the possibility that there will be a settlement—that would allow Sandoz to enter the market before Endo—is also too speculative to confer standing. Endo and Genzyme have *not* agreed to settle. To the contrary, the parties are actively litigating the '775 patent. Moreover, to the extent that Sandoz argues a mere possibility of settlement confers subject matter jurisdiction, it is wrong. The Federal Circuit held in *Jansen* that speculation regarding whether a first-filer will launch after FDA approval is insufficient to support a finding of subject matter jurisdiction. *Janssen*, 540 F.3d at 1362-63. There is no difference in principle between speculation regarding a delayed launch and speculation regarding settlement. Neither supports a finding of an injury in fact.

Sandoz's attempt to argue that this case is analogous to *Dey, L.P. v. Sepracor, Inc.*, 595 F. Supp. 2d 355 (D. Del. 2009), is similarly misguided. In *Dey*, the first-filer Breath *had settled* with the patentee Sepracor and *had agreed not to launch* its generic copy until August 2012, following the expiration of three of the six Orange Book-listed patents covering the innovative drug. *Id.* at 358. The second-filer, Dey, challenged all six of the Orange-Book listed patents; Sepracor brought suit on the five earliest-expiring patents. *Id*. Unless the court granted Dey the opportunity to challenge the sixth Orange Book-listed patent, it could not obtain final FDA approval of its generic copy until at least 180 days after Breath's settlement-delayed launch. *Id*. at 361-62. Thus, the second-filer faced a non-speculative delay in market entry well beyond the

first-filer's 180-day exclusivity if it was prevented from challenging the sixth patent—namely, from the date of any successful challenge to the five earliest-expiring Orange Book-listed patents until 180 days after Breath's settlement-delayed launch date. *Id*. at 362. That is not the case here. Again, Endo and Genzyme have *not* agreed to settle and speculation that a possible settlement agreement would include a delay in Endo's launch date, akin to that in *Dey*, cannot create a concrete injury in fact.

* * *

Citing the Supreme Court's decision in *Clinton v. City of New York*, 524 U.S. 417 (1998), Sandoz criticizes Genzyme for focusing on the possible outcomes to the several litigations before this Court. (Sandoz Opp'n 19-20.) This criticism is misplaced; the possible outcomes here demonstrate that dismissal of Sandoz's declaratory judgment action will not cause any justiciable delay in final FDA approval of Sandoz's ANDA. The only non-speculative delay Sandoz faces relates to Endo's 180-day exclusivity, which cannot create an injury in fact. (Genzyme Opening Br. 11-14.)

Moreover, *Clinton*, which concerned the constitutionality of the Line Item Veto Act, is simply not on point. *Clinton*, 524 U.S. at 420-21. There, the appellees *had* suffered a concrete and immediate injury—revival of a substantial contingent liability—by the President's veto of certain budgetary awards to the City of New York. Here, there is no concrete and immediate injury to Sandoz equivalent to that reversal. Sandoz's only identified "harm" results from Endo's alleged possible future inconsistent loss at trial or settlement with Genzyme. These future outcomes are—as the Supreme Court stated in *Clinton*—speculative and cannot support subject matter jurisdiction in this case. *Compare Clinton*, 524 U.S. at 431 ("Even if the outcome of the second trial is

speculative, the reversal, like the President's cancellation, causes a significant immediate injury by depriving the defendant of the benefit of a favorable final judgment.").

2. Allowing Sandoz To Enter The Market At The *Same Time* As Endo Is Contrary To The Goals Of The Hatch-Waxman Act

If Sandoz's declaratory judgment action is not dismissed and Sandoz prevails on noninfringement and/or invalidity of the '780 patent, Endo could forfeit its exclusivity. This would remove the regulatory bar to final FDA approval of Sandoz's ANDA presented by Endo's exclusivity. But, absent the baseless speculation regarding Endo's alleged possible future inconsistent loss at trial or settlement with Genzyme, Sandoz will *not* receive final approval *before* Endo. Rather, Sandoz could only receive final FDA approval at the *same time* as Endo, Lupin, Impax, and potentially other subsequent ANDA filers. Because Sandoz would not obtain final FDA approval before Endo, the *sole* effect of Sandoz's declaratory judgment action on the '780 patent would be the unjustified destruction of Endo's exclusivity. Contrary to Sandoz's assertions, such an outcome would frustrate the goals of the Hatch-Waxman Act. (Sandoz Opp'n 1, 2, 10, 11, 19, 22, 23.)

The Hatch-Waxman Act strikes a careful balance between dual goals of encouraging the development of innovative drugs and enabling the marketing of generic drugs. *Janssen*, 540 F.3d at 1361-62. To achieve this end, Congress awarded the *first* ANDA filer a 180-day period of generic market exclusivity. *Id.* In holding that delay caused by the first-filer's exclusivity did not create an Article III controversy, the Federal Circuit emphasized the importance of preserving this exclusivity period as an incentive to generic drug companies to challenge patents covering innovative drug products. *Id.* ("As the import of the 180-day exclusivity is clear, we hold that Apotex's exclusion from the

market because of Teva's entitlement to this statutory exclusionary period does not present a justiciable Article III controversy.").

In its Opposition, Sandoz too recognized the important purpose served by this period of market exclusivity. (Sandoz Opp'n 4 ("To incentivize generic pharmaceuticals to file ANDAs and thereby increase the volume of generic drugs on the market, the Hatch-Waxman Act grants 180 days of market exclusivity to the first generic pharmaceutical to file … a paragraph IV certification for a particular drug").)

Nonetheless, Sandoz repeatedly alleges that Genzyme is "gaming" the system and acting contrary to the intended result of the Hatch-Waxman Act by attempting to limit generic competition for Renagel® to Genzyme and Endo. (Sandoz Opp'n 1, 2, 10, 11, 20, 22, 23.) This baseless allegation that Genzyme is "gaming" the system is belied by the fact that two ANDA filers situated identically to Sandoz in this case—Lupin and Impax—have dropped their challenges to the '780 patent. (*Genzyme Corp. v. Lupin Ltd*., No. 09-cv-563 (Docket No. 44); *Genzyme Corp. v. Impax Labs*., No. 09-cv-653 (Docket No. 55).) Moreover, the period of limited competition about which Sandoz complains will only occur while Endo exercises its statutory right to 180 days of exclusivity which is an intended result of the Hatch-Waxman Act. This delay in FDA approval and market entry does not confer subject matter jurisdiction. *Janssen*, 540 F.3d at 1361-62.

It is important to remember that Sandoz was not the first generic company to file an ANDA containing a Paragraph IV certification. In fact, Sandoz was not even the second or the third such ANDA filer. Congress chose to grant only the first-filer a period of market exclusivity and Sandoz filed its ANDA too late to receive this statutory

reward. Given the clear absence of an injury in fact, Sandoz should not be able to frustrate the aims of the Hatch-Waxman Act by depriving Endo of the statutory benefit for its early filing.

II. The Court Has No Discretion To Hear Sandoz's Declaratory Judgment Action Because There Is No Actual Article III Controversy

In support of its claim that this Court should exercise its discretion to hear Sandoz's declaratory judgment claims, Sandoz repeats its groundless allegations of harm and delay. (Sandoz Opp'n 21-23.) As set out above, such allegations are false.

Sandoz also wrongly accuses Genzyme of manipulating the Court's jurisdiction in the manner discussed in *Merck*. (Sandoz Opp'n 22) (citing *Merck*, 488 F. Supp. 2d at 424-26, *affirmed-in-part, vacated-in-part as moot*, 287 F. App'x at 888-89 (Fed. Cir. 2008)). This case is very different from *Merck*. Here, Genzyme did not bring suit against Sandoz on the '780 patent and then later seek to divest this Court of jurisdiction by granting a covenant not to sue. Rather, Genzyme sued on only the '775 patent. It is Sandoz that wants this Court to address the additional '780 patent—even though it has not been asserted and a covenant not to sue has been granted—in the hope that Sandoz will thereby be able to destroy Endo's exclusivity. Sandoz alone seeks to impose unnecessary burdens on this Court and on Genzyme.

In any event, where—as here—there is no Article III controversy, the Court has no discretion to decide the case. *Spectronics Corp. v. H.B. Fuller Co.*, 940 F.2d 631, 633-34 (Fed. Cir. 1991) ("The existence of an actual controversy is an absolute predicate for declaratory judgment jurisdiction. When there is no actual controversy, the court has no discretion to decide the case. When there is an actual controversy and thus jurisdiction, the exercise of that jurisdiction is discretionary." (internal citation omitted)).

* * *

For the reasons set out above and in Genzyme's Opening Brief, there is no Article III controversy with respect to the '780 patent. The Court does not have subject matter jurisdiction over Sandoz's declaratory judgment action; Genzyme's motion should be granted.

Respectfully submitted,

KRAMON & GRAHAM P.A.

Dated: January 22, 2010

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